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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,670	04/24/2007	William T.H. Chang	U 016494-3	2796

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EXAMINER
KENNEDY, NICOLETTA

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,670	CHANG ET AL.	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/10 and 12/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-19 and 21-22 are currently pending.

Priority

This application, filed September 20, 2006, is a national stage entry of PCT/US2004/008768, filed March 23, 2004.

Withdrawn Objections/Rejections

1. The objections to claims 9-10 under 37 CFR 1.75(c) are withdrawn in view of Applicants' amendments.

2. The rejection of claims 1-4, 15 and 20 under 35 U.S.C. 102(b) over Sekigawa et al. (US 5,217,720) is withdrawn in view of Applicants' amendments.

3. The rejection of claims 1 and 15 under 35 U.S.C. 102(b) over Kudo et al. (US 6,972,132) is withdrawn in view of Applicants' amendments.

4. The rejection of claims 1 and 5-6 under 35 U.S.C. 103(a) over Sekigawa et al. (US 5,217,720) in view of Hashimoto et al. (US 5,474,989) is withdrawn in view of Applicants' amendments.

5. The rejection of claims 5-10 under 35 U.S.C. 103(a) over Sekigawa et al. (US 5,217,720) in view of Hashimoto et al. (US 5,474,989) and Cardinal et al. (US 4,895,724) is withdrawn in view of Applicants' amendments.

6. The rejection of claims 13-14 under 35 U.S.C. 103(a) over Sekigawa et al. (US 5,217,720) in view of Hashimoto et al. (US 5,474,989) and Bailly et al. (US 6,030,952) is withdrawn in view of Applicants' amendments.

7. The rejection of claim 16 under 35 U.S.C. 103(a) over Sekigawa et al. (US 5,217,720) in view of Hashimoto et al. (US 5,474,989), Cardinal et al. (US 4,895,724) and Frechet et al. (US 2002/0123609) is withdrawn in view of Applicants' amendments.

8. The rejection of claims 1, 11-12, 17-18 and 21 under 35 U.S.C. 103(a) over Kudo et al. (US 6,972,132) is withdrawn in view of Applicants' amendments.

9. The rejection of claim 19under 35 U.S.C. 103(a) over Kudo et al. (US 6,972,132) in view of Bolton et al. (US 4,814,178) is withdrawn in view of Applicants' amendments.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended independent claim 1 from the open language "comprising…an edible gum" to the closed language "consisting of…an edible gum." However, dependent claim 19 claims that the edible gum is **further** comprised of gelatin and Konjac gum. It is unclear whether this means that the capsule is comprised of three edible gums (a first gum and then the gums of claim 19) or of two gums (the gums of claim 19). With either interpretation, the use of "an edible gum," which indicates *one* edible gum, is inconsistent with dependent claim 19.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2, 15-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Preparation and release characteristics of polymer-coated and blended alginate microspheres, J. Microencapsulation, 2003, vol. 21, no. 2, p. 179-192).

Regarding claims 1-2, 15-16 and 21, Lee et al. teach a preparation of chitosan-blended alginate microspheres (p. 181 and p. 182(b)). The alginate was sodium alginate and the chitosan degree of deacetylation was 75 to 85% (p. 180-181). The only other components of the polymer-blended alginate microsphere were triethyl citrate (TEC), a food additive (p. 181) and the active agent (drug) (health-enhancing component).

With regard to the claim language “consisting of,” Lee et al. teach chitosan-blended alginate microspheres containing the optional ingredients of claim 1 and therefore, the microspheres of Lee et al. meet "consisting of" language of claim 1.

With regard to claim 21, the invention as claimed is not structurally distinguishable from Lee et al. and therefore it is the examiner’s position that the reduction of the mouth-puckering taste of chitosan is an inherent property of the composition as taught by Lee et al. See MPEP 2112.

Therefore, Lee et al. anticipate claims 1, 15 and 21.

13. Claims 1-6, 13, 15-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaserod et al. (Microcapsules of alginate-chitosan, Biomaterials 20 (1999) 773-783).

Regarding claims 1-6, 13, 15-16 and 21, Gaserod et al. teach alginate-chitosan capsules wherein the molecular weight was around 15,000 (abstract). The alginate was sodium alginate and the chitosan was chitosan hydrochloride (p. 774). In another example, the chitosan had a molecular weight of 62,000 (p. 777). The chitosans with molecular weights of 17,000 and 62,000 had a fraction of acetylation of less than 0.01 (p. 780).

With regard to claim 21, the invention as claimed is not structurally distinguishable from Gaserod et al. and therefore it is the examiner's position that the reduction of the mouth-puckering taste of chitosan is an inherent property of the composition as taught by Gaserod et al. See MPEP 2112.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-13, 15-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaserod et al. (Microcapsules of alginate-chitosan, Biomaterials 20 (1999) 773-783).

Regarding claims 1-6, 13, 15-16 and 21, Gaserod et al. teach alginate-chitosan capsules wherein the molecular weight was around 15,000 (abstract). The alginate was sodium alginate and the chitosan was chitosan hydrochloride (p. 774). In another example, the chitosan had a molecular weight of 62,000 (p. 777). The chitosans with molecular weights of 17,000 and 62,000 had a fraction of acetylation of less than 0.01 (p. 780). However, Gaserod et al. fail to teach a specific embodiment wherein the molecular weight of the chitosan may be from 100,000 to 200,000. The broad teachings of Gaserod et al. cure this deficiency.

Regarding claim 7, Gaserod et al. teach that the molecular weight of the chitosan may range from 1500 to 350,000 (p. 377). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range lies inside the range disclosed by Gaserod et al. and is therefore prima facie obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have used a molecular weight within the range claimed. One would have been motivated to do so because Gaserod et al. teach that the molecular weight of the chitosan was varied from 1500 to 350,000 to test capsule strength (p. 776-777).

Regarding claims 8-10, Gaserod et al. teach that the microcapsules had diameters from 200 to 4000 micrometers (p. 777). Although the chitosan particle size is not disclosed, it would have been within the purview of a skilled artisan to use chitosan particles within this range because the sodium alginate had a particle size of approximately 0.8 micrometers and the chitosan would be expected to make the bulk of the coating (p. 774-775).

Regarding claims 11-12 and 17-18, MPEP 2144.05 states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" quoting *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the instant case, Gaserod et al. teach a membrane comprising sodium alginate and chitosan. Although the workable

ranges of the weights are not disclosed, the MPEP states that discovering such ranges is not inventive.

With regard to claim 21, the invention as claimed is not structurally distinguishable from Gaserod et al. and therefore it is the examiner's position that the reduction of the mouth-puckering taste of chitosan is an inherent property of the composition as taught by Gaserod et al. See MPEP 2112.

Regarding claim 22, Gaserod et al. teach that the alginate solution is added to the chitosan solution and the complex alginate-chitosan membrane was formed instantaneously (p. 774-775). The liquid alginate core was then gelled by adding calcium chloride to the chitosan solution or adding it after the membrane was formed (p. 775). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann,* 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

18. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaserod et al. (Microcapsules of alginate-chitosan, Biomaterials 20 (1999) 773-

783) as applied to claims 1-13, 15-18 and 21-22 above, and further in view of Bailly et al. (US 6,030,953) (issued Feb. 29, 2000).

Gaserod et al. teach that the chitosan may be chitosan hydrochloride but fail to teach that the chitosan may be a C_8-C_{18} N-alkyl or C_8-C_{18} N-alkanoyl chitosan. Bailly et al. cure this deficiency.

Regarding claim 14, Bailly et al. teach a pharmaceutical composition containing chitosan wherein the chitosan may be a chitosan salt such as chitosan hydrochloride or a chitosan derivative such as a C_8-C_{18} N-alkyl or C_8-C_{18} N-alkanoyl chitosan (title and column 2, lines 9-26).

It would have been prima facie obvious to a person of ordinary skill in the art at time of the invention to have combined the teachings of Gaserod et al. with those of Bailly et al. to substitute a C_8-C_{18} N-alkyl or C_8-C_{18} N-alkanoyl chitosan for chitosan hydrochloride. One would have been motivated to do so because Bailly et al. teach that both chitosan hydrochloride and a C_8-C_{18} N-alkyl or C_8-C_{18} N-alkanoyl chitosan are used in pharmaceutical compositions to deliver active agents to the stomach (Bailly et al., column 2, lines 9-26).

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611